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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,648	11/13/2000	Dean M. Ponzi	37646/KMO/W112	7874

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EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/711,648	PONZI ET AL.	
	Examiner	Art Unit	
	Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,23-35,39 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,23-35,39 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to amendments submitted on 20 December 2006.

Double Patenting

1. Applicant is advised that should claims 1 and 23 be found allowable, claims 42 and 42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-15,17-20,23-25,27,28,30-35,39 and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by ABELE (US #5,403,311).

Regarding claim 1, Abele teaches "An injection catheter comprising: a catheter body (28) comprising a flexible tubing (30) having proximal and distal ends and at least one lumen (not labeled, Col 5 lines 47-65) there through; a tip section (e.g. 52) having a longitudinal axis and comprising a flexible tubing having proximal and distal ends,

wherein the proximal end of the tip section is mounted at the distal end of the catheter body (Fig 1, Fig 6); a needle control handle (17) at the proximal end of the catheter body; an injection needle (24) extending through the tip section, catheter body, and needle control handle and having a proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that upon suitable manipulation of the needle control handle the distal end of the injection needle can extend distally beyond the distal end of the tip section in a direction along the longitudinal axis of the tip section to penetrate tissue generally facing a distal face of the tip section (Fig 1); an electrode lead wire having a first end electrically connected to the injection needle (26) and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy (16), with a penetration monitoring electrode mounted on the injection needle." See also Col 3, lines 25-52, and Col 4 lines 19-29, and Col 5 lines 53-55.

Regarding claims 9 and 11, Abele teaches the limitations of claim 1 above, with the substitution and/or addition of an electrode mounted on the injection needle being electrically isolated for the injection needle. (Col 8 lines 50-Col 9 line 5).

Regarding claim 23, the claim recites the same limitations as claim 1 without explicitly defining the tip section. Examiner takes the proximal end of the catheter to be equivalent to the tip section of claim 1; therefore claim 23 is rejected under Abele.

Regarding claims 2,3,24, and 25, the electrode can be mounted at the distal or proximal end of the injection needle (52,56)

Regarding claims 5,6,27 and 28, Examiner takes the protective tube to be the cross-braided stainless steel filaments 30.

Regarding claims 7,14,19, and 46, Abele teaches the use of at least one additional electrode (Fig 10, 72 and 74)

Regarding claim 8, Abele teaches that the tip of the needle can be an electrode (Col 6 line 15)

Regarding claim 10, Abele teaches the use of a ring electrode (e.g. 26, Col 5 line 51)

Regarding the method claims 12,13,15,17,18,20,30-35,44,45, and 47, Abele describes various potential methods of use, disclosing all the of the claimed methods. See "Summary of the Invention" and "Description of Preferred Embodiments."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abele. Claim 16 specifies that the type of drug injected by the needle is selected from the group angiogenesis activators, angiogenesis inhibitors, and antiarrythmic drugs." Abele teaches the limitations of claims 12 and 1, but only specifies the use of a "vasoconstrictor, sclerotic, topical anesthetic, or heat responsive drug." Because Abele's catheter and the disclosed invention are both designed to be used to abate

tissue in the heart, the selection of one drug over another is a matter of obvious design choice.

5. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele as applied to claims 1 and 23 above, and further in view of COSMAN (US #4,966,597).

Abele teaches the limitations of a catheter for introduction into cardiac tissues, but does not teach the use of a pair of copper and constantan wires used as a thermocouple probe.

Cosman teaches the use of a thermocouple composed of copper and constantan wires (elements 1 and 5) in a cardiac catheter (Fig 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the electrode thermocouple probe of Cosman with the cardiac catheter of Abele is order to facilitate "true surface temperature recording with fast response" (Cosman Abstract)

Response to Arguments

Applicant's arguments filed 20 December 2006 have been fully considered but they are not persuasive. Applicant has argued that Abele does not teach a penetration monitoring electrode mounted on the injection needle. As disclosed in Abele Col 4 lines 65-68, the probe (24) is the penetration monitoring electrode. Further, Abele discloses in Col 5 lines 53-55 that the probe "Probe 24 has an extremely small dimension, sized to penetrate tissue, and in one embodiment includes a hollow needle with a central

sharp point". This meets the limitation that the penetration monitoring electrode is mounted on the injection needle.

Applicant has made no arguments regarding the combination of Abele and Cosman.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth MacNeill

11/27/07